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- 41 • **You have psoriasis (a skin disease) and it gets worse while taking PEGASYS**
- 42 • **High fever**
- 43 • **You have severe stomach pain or lower back pain**
- 44 • **Bloody diarrhea**

45
46 *For more information on possible side effects with PEGASYS therapy, please read the*
47 *section on "What are the possible side effects of PEGASYS?" in this Medication Guide.*

48 **What is PEGASYS?**

49 PEGASYS is a drug used to treat adults with lasting (chronic) hepatitis C and who show
50 signs that the virus is damaging the liver. Hepatitis C is a liver disease caused by the
51 hepatitis C virus. Hepatitis C is spread by contact with the blood of a person carrying the
52 hepatitis C virus. Hepatitis C is more serious for some people than others. Most people
53 who get hepatitis C carry the virus in their blood for the rest of their lives. Most of these
54 people will have some liver damage, but many do not feel sick from the disease. In some
55 people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis
56 can cause the liver to stop working.

57 In some patients that have received PEGASYS treatment for approximately one year, the
58 amount of the hepatitis C virus in the body was decreased to a level so low that it could
59 not be measured by blood tests. After 3 months of therapy, your healthcare provider may
60 ask you to have a blood test to help determine how you are responding to your treatment.

61 It is not known if PEGASYS can cure hepatitis C (permanently eliminate the virus) or if
62 it can prevent liver failure or liver cancer that is caused by hepatitis C infection.

63 There is no reason to believe that PEGASYS therapy will prevent a person with hepatitis
64 C from giving another person hepatitis C infection.

65 **Who should not take PEGASYS?**

66 Do not use PEGASYS if:

- 67 • You are pregnant or breast-feeding or are planning to become pregnant.
- 68 • You have autoimmune hepatitis (hepatitis caused by your immune system attacking
69 your liver).
- 70 • You have had an allergic reaction to other alpha interferons or are allergic to any of
71 the ingredients in PEGASYS (see ingredients listed at the end of this Medication
72 Guide).

73
74 **If you have ever had any of the following conditions or serious medical problems,**
75 **tell your healthcare provider before you start taking PEGASYS:**

- 76 • History of or current severe mental illness (such as depression or anxiety)
- 77 • History of drug or alcohol addiction or abuse
- 78 • History of heart disease or previous heart attack
- 79 • History of cancer

- 80 • Autoimmune disease (where the body's immune system attacks the body's own
81 cells), such as psoriasis (a skin disease), systemic lupus erythematosus, rheumatoid
82 arthritis
- 83 • Kidney problems
- 84 • Blood disorders
- 85 • You take a medicine called theophylline
- 86 • Diabetes (high blood sugar)
- 87 • Problems with the thyroid gland
- 88 • Liver problems, other than hepatitis C
- 89 • Hepatitis B infection
- 90 • HIV infection
- 91 • Colitis (an inflammation of the bowels)

92
93 You should tell your doctor if you are taking or planning to take other prescription or
94 nonprescription medicines or vitamin and mineral supplements and herbal medicines.

95 If you have any questions about your health condition or about taking PEGASYS, you
96 should talk to your healthcare provider.

97

98 **How should I take PEGASYS?**

99 PEGASYS is a ready-to-use solution given as a single injection once per week. Your
100 doctor may at some point change your dose of PEGASYS. Do not change your dose
101 unless your doctor tells you to change it. It is important to take PEGASYS exactly as
102 your healthcare provider tells you. Once you start treatment with PEGASYS, do not
103 switch to another brand of interferon without talking to your doctor. Other interferons
104 may not have the same effect on the treatment of your disease. Switching brands will also
105 require a change in your dose.

106 Your healthcare provider will train you and/or the person that will be giving you the
107 injections on the proper way to give injections. Whether you give yourself the injection
108 or another person gives the injection to you, it is important that you are comfortable with
109 preparing and injecting a dose of PEGASYS, and you understand the instructions in
110 "How do I inject PEGASYS?".

111 If you miss a dose and you remember **within 2 days** of when you should have taken
112 PEGASYS, give yourself an injection of PEGASYS as soon as you remember. Take your
113 next dose on the day you would usually take it. If **more than 2 days** have passed, ask
114 your healthcare provider what you should do.

115 If you take more than the prescribed amount of PEGASYS, call your healthcare provider
116 right away. Your doctor may want to examine you and take blood for testing.

117 You must get regular blood tests to help your healthcare provider check how the
118 treatment is working and to check for side effects.

119 **What should I avoid while taking PEGASYS?**

- 120 • Do not get pregnant while on PEGASYS treatment. PEGASYS may harm your
121 unborn child or cause you to lose your baby (miscarry).
122 • Do not breast-feed your baby while on PEGASYS treatment.
123

124 **What are the possible side effects of PEGASYS?**

125 Possible, serious side effects include:

- 126 • **Mental health problems including suicidal thoughts, blood problems, and body**
127 **organ problems:** See “What is the most important information I should know about
- 128 PEGASYS?”
- 129 • **Autoimmune problems:** Some patients may develop a disease where the body's own
130 immune system begins to attack itself (autoimmune disease) while on PEGASYS
131 therapy. These diseases can include psoriasis or thyroid problems. In some patients
132 who already have an autoimmune disease, the disease may worsen while on
133 PEGASYS therapy.
- 134 • **Heart problems:** PEGASYS may cause some patients to experience chest pain, and
135 very rarely a heart attack. Patients who already have heart disease could be at greatest
136 risk. Tell your healthcare provider if you have or have had a heart problem in the past.
137

138 **Common, but less serious, side effects include:**

- 139 • **Flu-like symptoms:** Most patients who take PEGASYS have flu-like symptoms that
140 usually lessen after the first few weeks of treatment. Flu-like symptoms may include
141 fever, chills, muscle aches, joint pain, and headaches. Taking pain and fever reducers
142 such as acetaminophen or ibuprofen before you take PEGASYS can help with these
143 symptoms. You can also try taking PEGASYS at night. You may be able to sleep
144 through the symptoms.
- 145 • **Extreme fatigue (tiredness):** Many patients may become extremely tired while on
146 PEGASYS therapy.
- 147 • **Upset stomach:** Nausea, taste changes, diarrhea, and loss of appetite occur
148 commonly.
- 149 • **Blood sugar problems:** Some patients may develop a problem with the way their
150 body controls their blood sugar and may develop diabetes.
- 151 • **Skin reactions:** Some patients may develop rash, dry or itchy skin, temporary hair
152 loss, and redness and swelling at the site of injection.
- 153 • **Trouble sleeping**

154

155 Talk to your healthcare provider if you are worried about side effects or find them
156 very bothersome.

157 **How do I inject PEGASYS?**

158 The following instructions will help you learn how to use PEGASYS vials. You should
159 read through all of these directions and get instructions from your healthcare provider
160 before trying to give yourself an injection. It is important to follow these directions

161 carefully. Talk to your healthcare provider if you have any questions about how to use
162 PEGASYS.

163 If you are giving this injection to someone else, a healthcare provider must teach you how
164 to avoid needle sticks. Being stuck by a needle can pass diseases on to you.

165 1. Collect all the materials you will need before you start to give the injection.

- 166 • One vial of PEGASYS
- 167 • A syringe and needle
- 168 • Several alcohol swabs
- 169 • A puncture-resistant container to dispose of the needle and syringe when you are
170 finished

171

172 2. Check the date on the carton the PEGASYS comes in and make sure the date has not
173 passed, then remove a vial from the package and look at the medicine.

- 174 • Do not use PEGASYS if:
 - 175 – the medicine is cloudy
 - 176 – the medicine has particles floating in it
 - 177 – the medicine is any color besides colorless to light yellow
 - 178 – if the expiration date has passed

179

180 3. Gently warm the refrigerated medicine by rolling it in the palms of your hands for
181 about one minute.

182 4. Wash your hands with soap and warm water to prevent infection.

183 5. Decide where you will give the injection.

- 184 • Pick a place on your stomach or thigh (see the picture below). Avoid your navel and
185 waistline. You should use a different place each time you give yourself an injection.



186

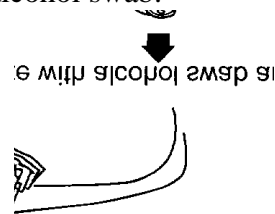
187 6. Prepare your skin for the injection.

- 188 • To minimize the discomfort from injections, you may want to gently tap the area
189 where you plan to give yourself an injection.
- 190 • Clean the area using the alcohol pad provided with PEGASYS. Let the skin dry for 10
191 seconds.

192

193 7. Get the vial of PEGASYS ready.

- 194 • Flip off the plastic top covering the vial opening, and clean the rubber stopper in the
195 vial opening with a different alcohol swab.



196

- 197 8. Get the syringe and needle ready.

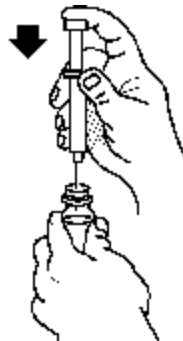
198 **If you are not sure how much medicine to use or which mark to use, STOP and call**
199 **your healthcare provider right away.**

- 200 • Remove the needle and syringe from their packaging.
201 • Attach the needle to the end of the syringe.
202 • Pull the syringe plunger back to the mark on the syringe barrel as instructed by your
203 healthcare provider. This will pull air into the syringe barrel.

FOR INTRAMUSCULAR USE

204

- 205 • Push the needle through the center of the stopper on the medicine vial.
206 • Slowly inject all the air from the syringe into the air space above the solution. Do not
207 inject air into the fluid.



208

- 209 • Keep needle in vial and turn both upside down. Hold vial and syringe straight up.
210 Slowly pull *back on the plunger until* the medicine is in the syringe up to the mark
211 specified by your healthcare provider. Make sure the needle tip is always in the
212 medicine (not in the air space above it) to avoid bubbles from forming in the syringe.



213

- 214 • When you have pulled up the medicine to the right mark, pull the syringe needle out
215 of the vial.

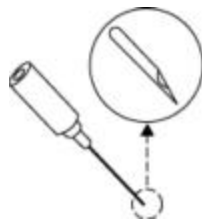
- 216 • Keep the syringe pointing up until you are ready to use it.
217 • If you need to set the syringe down, make sure the plastic shield covers the needle.
218 Never let the needle touch any surface.
219

220 9. Remove air bubbles from the syringe.

- 221 • Hold the syringe with the needle pointing up to the ceiling.
222 • Using your thumb and finger, tap the syringe to bring air bubbles to top.
223 • Press the plunger in slightly to push air bubbles out of the syringe.
224

225 10. Give the injection of PEGASYS.

- 226 • Position the point of the needle (the bevel) so it is facing up.
227



228

- 229 • Pinch a fold of skin on your stomach or thigh firmly between your thumb and
230 forefinger.
231



232

- 233 • Hold the syringe like a pencil at a 45° to 90° angle to your skin. In one quick motion,
234 insert the needle as far as it will go into the pinched area of skin. Pull the plunger of
235 the syringe back very slightly. If blood comes into the syringe, the needle has entered
236 a blood vessel. **Do not inject. Withdraw the needle and discard the syringe as**
237 **outlined in step 11. Repeat the above steps with a new vial and syringe and**
238 **prepare a new site.**

- 239 • If no blood appears, release your skin and slowly push the plunger all the way down
240 so that you get all of your medicine.
241

242



- 243 • Pull out the needle at same angle you put it in. Wipe the area with an alcohol pad.
244
245 11. For safety reasons, always promptly place used syringes and needles in a puncture-
246 resistant container immediately after use and never reuse them.

247

248 **How should I dispose of materials used to inject PEGASYS?**

249 If you use PEGASYS at home, you must throw away syringes and needles in a container
250 that will not let the needles stick through it. This will help protect you and other people
251 from accidental needle sticks. Being stuck by a needle not only hurts, but also can pass
252 diseases on to other people.

253 You can get these special boxes or containers, often called a "Home Sharps container,"
254 from your healthcare provider or pharmacist. There may be special state or local laws
255 about syringe disposal, so please check with your healthcare provider, nurse or
256 pharmacist for instructions.

257 **Do not throw full containers away in your household trash. Keep the container out**
258 **of the reach of children.**

259 **How should I store PEGASYS?**

260 PEGASYS must be stored in the refrigerator at a temperature of 36°F to 46°F (2°C to
261 8°C). Do not leave PEGASYS outside of the refrigerator for more than 24 hours. Do not
262 freeze PEGASYS. Keeping PEGASYS at temperatures outside the recommended range
263 can destroy the medicine.

264 Do not shake the vial of PEGASYS. If PEGASYS is shaken too hard, it will not work
265 properly.

266 Protect PEGASYS from light during storage.

267 Keep this and all other medicines out of the reach of children.

268 **General advice about prescription medicines**

269 Medicines are sometimes prescribed for purposes other than those listed in a Medication
270 Guide. If you have any concerns or questions about PEGASYS, contact your healthcare
271 provider. Do not use PEGASYS for a condition or person other than that for which it is
272 prescribed. If you want to know more about PEGASYS, your healthcare provider or
273 pharmacist will be able to provide you with detailed information that is written for health-
274 care providers.

275 Ingredients: peginterferon alfa-2a, sodium chloride, polysorbate 80, benzyl alcohol,
276 sodium acetate trihydrate, and acetic acid.

277 This Medication Guide has been approved by the U.S. Food and Drug Administration.



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